REMARKS

Applicants thank the Examiner for the helpful discussion of April 22, 2008.

Claims 1-5, 7-9 and 26 are pending. The listing of claims corresponds to the claims filed in the Amendment dated March 20, 2008, which was entered as indicated by the Examiner in the Advisory Action. Applicants respectfully request that the Examiner consider the following remarks as addressing the Advisory Action of April 11, 2008.

Claim Rejections – 35 USC § 112

Claims 1-5, 7-9 and 26 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement and for alleged lack of an enabling disclosure. Applicants respectfully disagree and strongly urge reconsideration and withdrawal of the rejections for the following reasons.

Written Description

The Examiner alleges that the specification fails to describe a representative number of genes encoding Δ5- and Δ8-desaturases and Δ9-elongase, and thus fail to satisfy the written description requirement. Specifically, the Examiner alleges that the prior art discloses only a limited number of genes encoding Δ5- and Δ8-desaturases, and that Δ9-elongase is not well known in the art at the time the invention was made. The Examiner therefore concludes that Applicants are not in possession of a method of using any Δ5- and Δ8-desaturases and Δ9-elongases. Applicants respectfully disagree.

The claimed subject matter relates to a **process** for production of polyunsaturated fatty acids by transforming Δ5-desaturase-, Δ8-desaturase-, and Δ9-elongase-encoding genes into a plant. As described in the specification at page 9, lines 6-15, the claimed process involves production of specific compounds in host cells which contain nucleic acids providing three functions: Δ-5-desaturase activity, Δ-8-desaturase activity, and Δ-9-elongase activity. Those functions are more clearly specified in the disclosure: C18 fatty acids with a double bond in Δ-9-position are elongated by the Δ-9-elongase, and double bonds are then introduced in Δ-8- and Δ-5-position of the resulting C20 fatty acids by Δ-8- and Δ-5-desaturase, respectively.

Thus, whether the nucleic acid sequences encoding polypeptides with Δ-5-desaturase activity, Δ-8-desaturase activity, and Δ-9-elongase activity comprises any particular nucleic acid

sequence, whether known or unknown at the time of filing, is not a critical feature of the claimed process, since any nucleic acid sequence encoding these functions would be operable in the claimed process.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

Possession of an invention can be shown "in a variety of ways, including description of an actual reduction to practice." See, "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement," at page A-6, 3d column of the "Written Description Training Materials." The present application describes an actual reduction to practice of the claimed process in Examples 10-11. Thus, possession of the claimed process is shown, and the rejection is improper and should be withdrawn for this reason alone.

Moreover, even viewing the individual elements of the process claim as defining those elements generically, disclosure of a species may be sufficient written description for a claim to a genus including that species. *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004). If the difference between members of the group (here, the sequences encoding the recited enzymes) is such that the person skilled in the art would readily recognize that other members of the genus would **perform similarly to the disclosed members**, then disclosure of more species is not necessary to show possession of the entire genus. *See Id.* Other Δ-5-desaturases, Δ-8-desaturases, and Δ-9-elongases would be expected to perform identically (perform the same enzymatic conversions) in the context of the claimed process. *See Bilstad*, 386 F.3d at 1124; *see also In re Rasmussen*, 650 F.2d 1212, 1215 (CCPA 1981)(disclosure of a single species within a genus satisfies the written description requirement for a generic claim because one skilled in the art, in reading the specification, would understand that it is unimportant how the layers are adhered, so long as they are adhered).

As to a particular claim element, an applicant need not describe that claim element in the level of detail that the particular invention warrants. It is only necessary that the description be sufficiently clear that persons skilled in the art would have recognized that the applicant made the invention having those limitations. *In re Wertheim*, 191 USPQ 90, 96 (CCPA 1976).

For all of these reasons, one skilled in the art, reading the present application, would clearly see possession of the claimed process irrespective of the particular sequences used, so long as those sequences encode polypeptides having the required enzymatic activities. In view of the nature of the invention, limiting the invention to the working examples using particular sequences is fundamentally unfair to applicants and would defeat meaningful patent protection.

Please also note that granting the subject process claims only prevents the public from using the recited nucleic acid sequences in the context of the claimed process. For this reasons, there is a clear distinction from *Eli Lilly*, since a product claim prevents others from using the claimed product for any reason.

Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement

The Examiner further rejects the claims based on the specification allegedly not being enabling for any transgenic plant expressing any Δ-5- and Δ-8-desaturases and any Δ-9-elongase, arguing that identification and isolation of the allegedly unexemplified genes encoding Δ5- and Δ8-desaturases and Δ9-elongase is undue and unpredictable. Applicants respectfully disagree.

As discussed above, the claimed subject matter relates to a **process** and the individual genes encoding Δ5-desaturase, Δ8-desaturase, or Δ9-elongase are not being claimed. Rather, the claimed subject matter concerns the use of these genes in a particular way to produce polyunsaturated fatty acids in transgenic plants (*i.e.* the "nature of the invention" *Wands* factor is the process, not the genes).

The specification, by way of Examples 10-11, describes how to make and use the claimed process, illustrating an actual reduction to practice. Thus, the "presence of absence of working examples" and "amount of guidance" *Wands* factors clearly support enablement.

The level of skill is high, which supports enablement.

As to the scope of the claims, it is correct that the broadest claims encompass any Δ-5- and Δ-8-desaturases and any Δ-9-elongase. However, the need for routine screening to identify functional variants or homologs operable in the claimed process does not defeat enablement. *In re Wands*, 8 USPQ 2d at 1404 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). As pointed out in the Amendment And Reply

Under 37 CFR §1.116 dated March 20, 2008, at page 8, for example, it is routine experimentation to identify other Δ-9-elongases, using the instantly-disclosed sequence as a probe. As to the "quantity of experimentation needed" *Wands* factor, it is clear that the needed experimentation is not undue.

For these reasons, undue experimentation is not required to make and use the claimed process. Reconsideration and withdrawal of the rejection is respectfully requested.

The Examiner further rejects the claims as nonenabling for producing any compounds of formula I other than C20 polyunsaturated fatty acids. According to the Examiner's interpretation, the specification enables only for a method for **accumulating** C20 polyunsaturated fatty acids in transgenic plants. For support, the Examiner points to Table 1 at page 50 where certain C16 and C18 fatty acids were produced in a lesser amount in transgenic plants than in wild type plants. Applicants respectfully traverse.

As discussed in the Amendment And Reply Under 37 CFR §1.116 dated March 20, 2008, the claimed process is directed to production of compounds of formula I in a transgenic plant "**with a content of at least 1% by weight of said compounds in reference to the total lipid content of said plant.**" As shown in Table 1 at page 50, the triple transformed plants produced various types of fatty acids including C16, C18, and C20 polyunsaturated fatty acids, each of these fatty acids has a content of more than 1% by weight in reference to the total lipid content of the plant. Thus, not only C20 polyunsaturated fatty acids are produced and accumulated in the transgenic plants, other polyunsaturated fatty acids such as C16 and C18 polyunsaturated fatty acids are also produced in the transgenic plants. Even if the production of C16 and C18 polyunsaturated fatty acids are in an amount less than what observed in the wild type, the production of these polyunsaturated fatty acids in the triple transformed plants are nonetheless more than 1% by weight in reference to the total lipid content of the plant. Accordingly, the specification is clearly enabling for the claimed subject matter. Reconsideration is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Accompanying this response is a Request for Continued Examination and a petition for a one-month extension of time to and including May 23, 2008 to respond to the Office Action mailed January 23, 2008 with the required fee. No further fee is believed due. However, if any additional fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 13478-00001-US from which the undersigned is authorized to draw.

Respectfully submitted,

By_____

Hui-Ju Wu, Ph.D.
Registration No.: 57,209
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P. O. Box 2207
Wilmington, Delaware 19899-2207
(302) 658-9141
(302) 658-5614 (Fax)
Agent for Applicants

#613044